

**REMARKS**Telephone Interview

Applicants would like to thank Examiner Yunsoo Kim for the phone conference held with Applicants' representative on April 16 and 25, 2007. During the phone interview, the new matter rejection was discussed. The Examiner stated she will present our written arguments to her supervisor for a final decision.

Title

The title has been amended to more clearly describe the claimed invention.

Status of the Claims

Claims 257-362 are currently pending in the present application. Claims 1-256 have been canceled without prejudice or disclaimer of the subject matter claimed therein. New claims 257-362 have been added. As shown in the table below, new claims 257-362 correspond closely to claims 162-256. Additional claims (281, 283, 286, 292, 317, 319, 322, 328, 353, 355, and 360) have been added. Representative support for these additional claims is provided in the table below. Claims 274, 288, 310, 324, 346, and 356 include additional features not present in the corresponding claims that have been canceled. Representative support for these additional features is provided in the table below. New claims 257-362 do not introduce prohibited new matter.

Claim(s)	Representative Support
257	Claim 162; Page 3, lines 29-31
258, 294	Claims 163, 195
259, 295	Claims 164, 196
260, 296	Claims 165, 197
261, 297	Claim 166, 198
262, 298	Claim 167, 199
263, 299	Claim 168, 200
264, 300, 336	Claims 169, 201, 233; Page 8, lines 29-31; Page 7, lines 7-10

265, 301, 337	Claims 170, 202, 234
266, 302, 338	Claims 171, 203, 235; Pages 24-26
267, 303, 339	Claims 172, 204, 236; Page 24, line 26
268, 304, 340	Claims 173, 205, 237
269, 305, 341	Claims 174, 206, 238; Page 25, line 22
270, 306, 342	Claims 175, 207, 239
271, 307, 343	Claims 176, 208, 240; Page 7, lines 7-10
272, 308, 344	Claims 177, 209, 241; Page 9, line 26 and pages 24-26
273, 309, 345	Claims 178, 210, 242; Page 24, line 26
274, 310, 346	Claims 179, 211, 243 ; Page 9, lines 2-4, 8-10
275, 311, 347	Claims 180, 212, 244; Page 24, line 26
276, 312, 348	Claims 181, 213, 245
277, 313, 349	Claims 182, 214, 246; Page 25, line 22
278, 314, 350	Claims 183, 215, 247
279, 315, 351	Claims 184, 216, 248; Page 23, line 16
280, 316, 352	Claims 185, 217, 249
281, 317, 353	Claim 173; Example 18
282, 318, 354	Claims 186, 218, 250; Page 9, lines 15-18
283, 319, 355	Claims 176, 186; Page 9, lines 15-18
284, 320	Claims 187, 219
285, 321	Claims 188, 220
286, 322,	Page 26, lines 17-22; Example 18
287, 323	Claims 189, 221
288, 324, 356	Claims 190, 222, 251; Page 9, lines 15-18; Page 26, line 23 to Page 27, line 32; Page 53, lines 20-22
289, 325, 357	Claims 191, 223, 252; Page 32, line 13
290, 326, 358	Claims 192, 224, 253; Page 5, line 1
291, 327, 359	Claims 193, 225, 254; Page 6, lines 1-5
292, 328, 360	Page 9, lines 2-4, 8-10; Page 29, line 29

293	Claim 194; Page 7, lines 27-30; Page 8, line 20; Page 11, lines 3-14; Page 12, lines 22-24; Page 14, lines 4-6, lines 24-30; Page 21, lines 17-22
329	Claims 142, 226
330	Claims 143, 227
331	Claims 145, 228
332	Claims 146, 229
333	Claims 147, 230
334	Claims 148, 231
335	Claims 149, 232
361	Claims 161, 255
362	Claims 159, 256

Rejections of the Claims Under 35 U.S.C. § 112, First Paragraph

Claims 194-225 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification as to convey that the inventors had possession of the claimed invention (New Matter rejection).

The Office Action asserts that “concurrently” treating and applying a formulation in claim 194 is considered new matter.

Claims 194-225 have been canceled and replaced with new claim 293-328. Applicants respectfully point out that representative support for claim 293 can be found on page 7, lines 27-30; page 8, line 20; page 11, lines 3-14; page 12, lines 22-24; page 14, lines 4-6 and lines 24-30; and page 21, lines 17-22. For example, page 7, lines 27-30 teach that the patch may comprise an effective amount of antigen and adjuvant and that the patch may be an occlusive dressing, may contain penetration enhancers or may include a device for penetration enhancement. This passage discloses concurrently treating the skin with a penetration enhancer or with a device for physical penetration enhancement and applying a formulation comprising the antigen and adjuvant, since the patch comprises a penetration enhancer (or a device) and the formulation. Also, page 8, lines 20 and 21 teach that a formulation may comprise a vehicle and page 11, lines 3-14 teach that the use of vehicles to increase hydration is well known, for example, the

occlusive dressing. Thus, this passage of the specification also teaches concurrently treating the skin to enhance penetration with applying a formulation. Likewise, page 14, lines 24-30 disclose formulations comprising an antigen, an adjuvant, and penetration enhancers. As another example, page 12, lines 22-24 teach that in the present invention, the needles of a device used for disruption of the stratum corneum may be coated with antigen and adjuvant and applied to the skin. Thus, this passage also teaches concurrently treating the skin for barrier disruption and applying the formulation comprising the antigen and adjuvant. Furthermore, page 21, lines 17-22 disclose applying antigen in a hydrating solution or occlusive patch to the skin, which also teaches simultaneously treating the skin and applying an antigen formulation. Accordingly, the specification teaches concurrently treating the skin and applying a formulation transcutaneously.

Moreover, Applicants respectfully point out that the term “concurrently” is used in the specification, for example on page 14, line 6. Likewise, the terms “in conjunction with” (page 14, lines 6) and “simultaneously” (page 21, line 21) are also used in the specification. These terms are used in connection with transcutaneous immunization, penetration enhancement, and activation of the skin.

Thus, since the specification teaches concurrently treating the skin and applying a formulation comprising an antigen and the term “concurrently” is used in the specification in describing penetration enhancement and transcutaneous immunization, claim 293 and its dependent claims do not include prohibited new matter.

#### Double Patenting Rejection

Claims 162-193 and 226-256 are rejected under the judicially created doctrine of double patenting over pending claims 1-16 of U.S. Patent No. 7,037,499.

Claims 162-193 and 226-256 have been canceled and replaced with claims 257-292 and 329-362.

On November 8, 2005, Applicants submitted a terminal disclaimer disclaiming the terminal part of the statutory term of any patent granted on Application 10/790,715, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §§154, 156, 173, as presently shortened by any terminal disclaimer, of any patent granted on pending reference Application 09/266,803. Application 09/266,803 has now issued as U.S. Patent

7,037,499. Applicants respectfully submit that a new terminal disclaimer is not required.

Claims 194-225 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,037,499 in view of U.S. Patent No. 4,865,848.

Claims 194-225 have been canceled and replaced with claims 293-328.

For the reasons set forth above, Applicants respectfully submit that a new terminal disclaimer is not required.

Since U.S. Patent 4,865,848 ('848) is directed to transdermal delivery of small molecules, U.S. Patent '848 by itself does not render the claimed invention obvious. Accordingly, Applicants request withdrawal of the rejection.

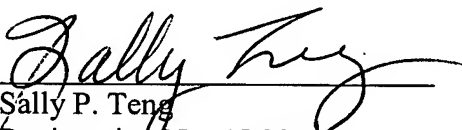
#### Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, she is invited to telephone the undersigned at their convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,  
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